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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,564	09/04/2001	Nedaa Abdul-Ghani Nasif		8476

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MEYER UNKOVIC & SCOTT LLP
1300 OLIVER BUILDING
PITTSBURGH, PA 15222

EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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11/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/944,564

Applicant(s)

NASIF, NEDAA ABDUL-GHANI

Examiner

Patrick T. Lewis

Art Unit

1623

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-43 is/are pending in the application.
- 4a) Of the above claim(s) 28-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27 and 35-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C2)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 23, 2008 has been entered.

Election/Restrictions

2. Applicant's election with traverse of Group I in the reply filed on August 4, 2004 is acknowledged. The requirement was made FINAL in the Office Action dated November 21, 2005.
3. Claims 28-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 4, 2004.

Applicant's Responses Dated June 23, 2008 and September 2, 2008

4. Claims 27-43 are pending. Claims 28-34 are withdrawn from further consideration. An action on the merits of claims 27 and 35-43 is contained herein below.
5. Applicant's arguments with respect to the rejection of claim 27 under 35 U.S.C. 102(b) as being anticipated by Sanchez Palacios A. et al. Allergol Immunopathos (Madr), (1992), Vol. 20 (1), pages 35-39 (Sanchez) have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claims 27 and 35-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanchez Palacios A. et al. Allergol Immunopathos (Madr), (1992), Vol. 20 (1),

pages 35-39 (Sanchez); Hall et al. Mandell, Douglas, and Bennett's Principles and Practice of Infectious Diseases, Sixth Edition (2005), Chapter 60, pages 812-819 (Hall); and Annesi-Maesano I. Allergy (1999), Vol. 54, Suppl. 57, pages 7-13 (Annesi) in combination.

Claims 27 and 35-43 are drawn to a method of treating allergy and asthma patients comprising administering a pharmaceutical composition consisting essentially of glycosphosphopeptical in multiple doses for a period of 1-20 days.

Sanchez discloses the use of immunoferon (AM3) in the treatment of childhood infectious respiratory pathology. To assess the immunoclinical effectiveness of a biological response immunomodulator, glycosphosphopeptide (AM3) was administered to 20 children with asthmatic bronchitis. The children received 2 envelopes (1 g) daily for 4 months. The clinical and immunological parameters assessed were: cough, dyspnea, expectoration, frequency and intensity of the bronchospasm, time of administration of the symptomatic medication, and the delayed cutaneous cells response by means of the intradermal reaction of 5 antigens. Immunoferon reduced the symptoms, the intensity and frequency of the bronchospasm, and the symptomatic medication.

Sanchez differs from the instantly claimed invention in that Sanchez is directed to the treatment of asthmatic bronchitis. Sanchez also differs from the instant invention in that Sanchez teaches a longer treatment period.

Hall teaches that bronchiolitis is an acute viral lower respiratory tract illness that occurs during the first 2 years of life (page 812). The illness also has been called

"wheezy bronchitis" and "asthmatic bronchitis". Whatever term is applied, the syndrome is caused primarily by viral infections. The characteristic clinical manifestations include an acute onset of wheezing and hyperinflation, most commonly associated with cough, rhinorrhea, tachypnea, and respiratory distress. Clarifying the relationship between bronchiolitis and subsequent asthma is complicated by confusion about the pathophysiology of asthma itself (page 815). Asthma is a heterogeneous group of disorders engendered by multiple factors, both genetic and environmental. These include not only an atopic predisposition and the environmental risk factors but also specific genetic polymorphisms. Nevertheless, the disorders in this heterogeneous group share, in various combinations, wheezing, reversible airway obstruction, airway inflammation, and structural airway wall remodeling.

Annesi teaches that the major difficulty in the study of the relationship between upper and lower airway disease comes from the fact that asthma, rhinitis and sinusitis constitute heterogeneous disorders for which no standardized definitions are available to be used in epidemiological settings (page 7). Asthma is both extrinsic (allergic) and intrinsic (nonallergic), for which no IgE-mediated process is proven; rhinitis is infectious, allergic (seasonal or perennial), or noninfectious, nonallergic; sinusitis is classified as acute or chronic. No consensus exists on the definition of these conditions. Furthermore, no gold standard has been assessed for diagnosing them. It is well known that upper and lower airway diseases coexist in many patients (page 8). Classically, allergic rhinitis has been linked with extrinsic asthma and nonallergic rhinitis, with asthma beginning in adulthood and for which there is no provable atopy. Allergic

rhinitis and extrinsic asthma occur together more often than expected by chance. The common association of sinus disease with asthma has been known many years. Sinusitis has been linked to allergic rhinitis, asthma and nasal polyps. Sinusitis is commonly associated with asthma and evidence is accumulating that there may be a cause-and-effect relationship; that is, that sinusitis triggers or aggravates asthma.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to treat allergy and asthma patients using the method of Sanchez because of the overlapping symptoms. Although, Sanchez teaches the treatment of asthmatic bronchitis vs. asthma, no consensus exists on the definition of these conditions. Sanchez teaches the treatment of asthmatic bronchitis in which the characteristic clinical manifestations include an acute onset of wheezing and hyperinflation, most commonly associated with cough, rhinorrhea, tachypnea, and respiratory distress. Asthma is a heterogeneous group of disorders which share, in various combinations, wheezing, reversible airway obstruction, airway inflammation, and structural airway wall remodeling.

Conclusion

9. Claims 27-43 are pending. Claims 28-34 are withdrawn from further consideration. Claims 27 and 35-43 are rejected. No claims are allowed.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patrick T. Lewis/
Primary Examiner, Art Unit 1623

/PTL/